



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 30 1999

Food and Drug Administration
Rockville MD 20857

1488 '99 AUG -2 P1:18

Mr. Sas Weber
111055 Gee-Norman Rd.
Belgrade, MT 59714

Dear Mr. Weber:

This is in response to your letter dated June 14, 1999, concerning the use of recombinant Bovine Growth Hormone (rBGH) in dairy cows.

Thank you for sharing your concerns on this issue. The use of drugs in livestock and poultry is strictly regulated. Before any drug intended for use in animals is approved, it must undergo extensive chemical and toxicological testing which must demonstrate that the food from these animals is safe for human consumption.

Bovine somatotropin (bST) was approved by the Food and Drug Administration (FDA) in 1993. The recombinant, or genetically engineered form of bST (rbST) is virtually identical to a cow's natural somatotropin, a hormone produced in its own pituitary gland that stimulates milk production. Since bST is a protein-based hormone, rbST is broken down during digestion, which makes it biologically inactive and incapable of having any effect in humans or animals. Over 120 studies were reviewed by FDA scientists that examined the safety of milk and meat from dairy cows treated with rbST. They concluded that there was no increased health risk to consumers.

I am enclosing materials which provide further information concerning this matter. In addition, I am forwarding your letter to Dockets Management Branch for inclusion in Docket Number 98P-1194 -- Withdrawal of NADA Approval for Posilac -- rBGH. Please visit our Internet Home Page at <http://www.fda.gov/cvm>.

Sincerely yours,

Karen A. Kandra
Consumer Safety Officer
Center for Veterinary Medicine

Enclosures

98P-1194

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C198 ANS

Monday, July 26, 1999
Page Number : 1

DUE DATE : 8/22/99

TracNumber :

Rec'd Date : 7/22/99

Doc Date : 6/14/99

To: CDER

From : WEBER, SAS

Affiliation :

Address :

CorrType : letter

Subject:
URGING THE FDA TO
REMOVE BOVINE GROWTH
HORMONE (RBGH) IN DAIRY
COWS

[illegible]

FYI

Office	OfficeName
CVM	

Comments :

URGING FDA TO REMOVE BOVINE GROWTH HORMONE (RBGH) IN DAIRY COWS

JUNE 14 1999

DEAR SIRs WHO MAY BE CONCERNED —

I AM WRITING TO INFORM YOU OF MY DISAPPROVAL
OF YOUR POLICY ALLOWING THE USE OF
RECOMBINANT BOVINE GROWTH HORMONE (rBGH)
IN DAIRY COWS.

CONSIDERING THE RISKS AND UNANSWERED
QUESTIONS, THE NEGLIGIBLE GAIN, AND THE FACT THAT
NO OTHER INDUSTRIALIZED COUNTRY HAS APPROVED
ITS USE, YOUR ~~TO~~ POLICY IS UNCONSCIONABLE.

I HOPE ENOUGH PUBLIC OUTCRY WILL ~~TO~~ HELP
SWAY YOU TO REVERSE YOUR POLICY.

THANK YOU IN ADVANCE FOR LISTENING.

Yours —

SAS WELSON

~~SAS~~

11056 GEE NORMAN RD

BELGRADE MT

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Weber
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Belgrade, Montana 59714



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FDA

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